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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,976

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

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3762

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/748,976	<b>Applicant(s)</b> YUN ET AL.	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 17-30 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-20 and 39-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 4, 7, 9, 10, 17, 18, 20, 39-42, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai (US 2005/0065574, hereinafter "Rezai") in view of Ideker et al. (US 5,522,854, hereinafter "Ideker"). Please note that Examiner has confirmed "Table II" of Rezai's disclosure is supported by its presentation in PCT/US03/02847, which is currently unpublished.

4. In regards to claims 1, 17, 18, and 40-42, Rezai discloses modulating a portion of the autonomic nervous system of a female subject known to suffer from a fertility condition with an implanted device (20). Because the therapy is applied "to affect the

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hypothalamic-related condition” (par. 0006), and the hypothalamic-related conditions, including infertility and irregular/painful menses are listed in Table II, Rezai inherently discloses, “providing a female subject known to suffer from said fertility condition”.

Alternatively, it is well known to provide a patient having a pathological state with a particular therapy that is known to be an effective treatment for said pathological state to improve the wellbeing of the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Rezai’s method with the step of providing a female patient known to suffer from a fertility condition to effectively treat said fertility condition and to improve the wellbeing of the patient.

5. Further, Rezai’s invention is capable of increasing the sympathetic activity/parasympathetic activity ratio of the subject, and is capable of treating a fertility condition (Table II, line 1 indicates “infertility” and “irregular/painful menses”, which means the device is applied to a female). For evidence that hypothalamus stimulation will result in increasing said ratio, please refer to US 4,339,384 (Maillard et al.), column 8, line 34. Additionally, any stimulation of the autonomic system that increases the ratio of sympathetic activity to parasympathetic activity will inherently treat a fertility condition. Further, Rezai discloses a closed-loop feedback mechanism (par. 0047) that will determine a variable (from the sensor) before, during, and after modulation because it is running in a loop fashion. Rezai does not disclose that the variable is the ratio of sympathetic activity to parasympathetic activity. Ideker teaches a method of providing modulation to a hypothalamus-controlled physiological function (col. 1, lines 27-32) with

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feedback comprising the sensing ratio of sympathetic and parasympathetic nervous system conduction (col. 3, lines 38-42) with an implanted electrode (Fig. 1) to provide the predictable result of determining an imbalance in nervous system activity that can cause a clinically detrimental result. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's device by monitoring a variable comprising the ratio of sympathetic and parasympathetic nervous system activity with an implanted electrode to provide the predictable result of controlling a device by determining an imbalance in nervous system activity that can cause a clinically detrimental result.

**6.** In regards to claims 4 and 10, the increase in the ratio comprises increasing sympathetic activity (see Maillard).

**7.** In regards to claims 7 and 39, the modulation is localized to the hypothalamus (Fig. 1), which is preganglionic.

**8.** In regards to claim 9, electrical energy is applied to the autonomic nervous system (abstract). Since the hypothalamus controls the autonomic nervous system, Examiner is interpreting the hypothalamus to be part of the ANS.

**9.** In regards to claim 20, the fertility condition is infertility (Table II, line 1).

**10.** In regards to claims 45 and 46, Rezai and Ideker disclose the essential features of the claimed invention, including treating ovulation-related disorders, but do not disclose providing modulation for a period of days or weeks. It is well known in the medical arts to treat disorders of the human estrus cycle on the scale of several days to weeks. Therefore, it would have been obvious to one having ordinary skill in the art at

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the time the invention was made to further modify Rezai's device by modulating for a period of days or weeks, consistent with the time scale of the human estrus cycle as this would be applying a known technique to a known device to yield predictable results.

**11.** Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as obvious over Rezai in view of Ideker, as applied to claim 1 above, or in the alternative, over Rezai and Ideker and further in view of Bothe Loncar et al. (US 2002/0188336, hereinafter "Bothe").

Rezai discloses the essential features of the claimed invention, including providing stimulation continuously (par. 0042), which would inherently provide modulation during the luteal phase. Alternatively, Rezai does not explicitly specify performing modulation during the luteal phase of the menstrual cycle. Bothe teaches of providing ANS modulation during the luteal phase of the menstrual cycle (par. 0264) to provide the predictable results of enhancing the functions of the specific phase where pregnancy occurs. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by modulating the ANS during the luteal phase to provide the predictable results of enhancing the functions of the specific phase where pregnancy occurs.

**12.** Claims 5, 6, 11, 43, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Ideker, as applied to claim 1 above, and further in view of Whitehurst et al. (US 6,832,114, hereinafter "Whitehurst"). Rezai and Ideker disclose the essential features of the claimed invention except for modifying the ratio by electrically decreasing parasympathetic activity or increasing sympathetic activity and decreasing parasympathetic activity. Whitehurst teaches of ANS modulation achieved

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by electrically inhibiting parasympathetic stimulation and/or activating sympathetic stimulation (col. 18, line 60) to more accurately modulate the innervated organ. Further, it is well known in the electrical therapy arts to inhibit neurological function by ablating specific nerves to provide the predictable result of permanently treating abnormal neurological behavior. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai and Ideker's invention by providing ANS modulation by electrically inhibiting parasympathetic stimulation and/or activating sympathetic stimulation to provide the predictable results of more accurately modulating the innervated organ, and to inhibit neurological function by ablating specific nerves to provide the predictable result of permanently treating abnormal neurological behavior.

**13.** Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Ideker, as applied to claim 1 above, and further in view of Mann et al. (US 2002/0055761, hereinafter "Mann"). Rezai and Ideker disclose the essential features of the claimed invention except for stimulating the pelvic nerve. Mann teaches of stimulating a pelvic nerve (par. 0076) to more locally treat a fertility condition so as to not affect other systems of the body (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rezai's invention by stimulating a pelvic nerve to provide the predictable results of more locally treating a fertility condition so as to not affect other systems of the body.

**14.** Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rezai in view of Ideker, as applied to claim 1 above, and further in view of Khan et al. (US

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2002/0064501, hereinafter "Khan"). Rezai and Ideker disclose the essential features of the claimed invention except for determining the ratio of Th1 to Th2. Khan teaches of regulating the Th1/Th2 ratio to facilitate fertility where improved implantation is required. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rezai's invention by determining the ratio of Th1 to Th2 to provide the predictable results of further facilitating fertility.

### ***Response to Arguments***

**15.** Applicant's arguments filed 11/24/2008 have been fully considered but they are not persuasive. Applicant argued that neither Rezai nor Ideker teach the element of "increasing the sympathetic activity/parasympathetic activity ratio in a manner effective to treat a female subject for a fertility condition," and that Rezai merely teaches stimulation of the hypothalamus for treatment of a wide variety of conditions. Applicant further argued that Ideker is directed to a method of preventing arrhythmia by measuring heart rate variability, thus is not applicable to treating a fertility condition and any motivation to combine would then be for the treatment of arrhythmia, not a female fertility condition. However, Rezai does increase the sympathetic activity/parasympathetic activity ratio, regardless of whether this effect was realized at the time. *See Maillard* (US 4,339,384; col. 8, lines 33-36). Further, Rezai discloses that any of a number of variables may be utilized in a closed-loop manner to modulate the applied stimulation (par. 0048), including "the rate and pattern of the neuronal electrical activity," and that corresponding sensors can be located in relevant neural structures including "the spinal cord, cranial nerves, and/or spinal nerves" (par. 0050). Rezai is



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merely lacking explicit teaching that the "pattern of neuronal electrical activity" is the sympathetic activity/parasympathetic activity ratio. Taken as a whole, the evidence of Maillard (which establishes that stimulation of the hypothalamus affects this ratio), and Ideker's prior art teaching of monitoring the ratio in the respective nerves that innervate an organ controlled by the hypothalamus (col. 3, lines 40-47 and col. 1, lines 27-32) to provide closed-loop control renders the results predictable. In regards to the argument that Rezai does not even disclose the feedback suggested by Ideker for Rezai's arrhythmia embodiment, the examiner is not relying in any way on Rezai's arrhythmia embodiment. Although combining various embodiments of Rezai with various embodiments of Ideker may or may not result in the claimed subject matter, the examiner is relying on Rezai's fertility-treating embodiment using closed-loop feedback of neuronal activity patterns. The examiner maintains that the application of Ideker's variable (sympathetic/parasympathetic ratio) to Rezai's invention is a simple substitution of one known element for another to obtain predictable results.

**16.** Applicant further argued that neither Rezai nor Ideker teach modulation for a period of days or weeks, or electrically inhibiting by ablation. The corresponding claims (44-46) were rejected under Rezai, Ideker, and well-known teachings. Please see Bothe Loncar (US 2002/0188336; par. 0264) as one of many teachings of modulating fertility function over a period of days or weeks, and Verrier (US 5,437,285; col. 27, lines 29-58) is one of many teachings of electrically inhibiting nerves by ablation.

***Conclusion***

**17. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/  
Examiner, Art Unit 3762

/Angela D Sykes/  
Supervisory Patent Examiner, Art Unit 3762